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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,707	08/05/2003	W. Jean Dodds	58034-011800	8325

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EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
12/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/635,707	DODDS, W. JEAN	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,8-10,12,14,17,18,25 and 40-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 8-10, 12, 14, 17-18, 25, and 40-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims Under Examination

Claims 1, 3-5, 8-10, 12, 14, 17-18, 25, and 40-45 are under examination. Claims 2, 6-7, 11, 13, 15-16, 19-24, and 26-39 are cancelled.

Withdrawn Rejections

The rejection of claims 40-45 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's amendments to the claims, filed 09/07/2007.

The rejection of claims 1, 3-5, 8-10, 12, 14, 17-18, and 40-41 are rejected under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendments to the claims, filed 09/07/2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5, 8-10, 12, 14, 17-18, 25, and 43 are rejected under 35 U.S.C. 103(a) as being made obvious by Dodds (US 6,287,254; Issued: Sept. 11, 2001), in view of Trendelenburg et al. (Clinica Chimica Acta, 1998, Vol. 278, p. 229–242).

Dodds teaches a veterinary diagnostic method, system and apparatus of health profiling of an animal subject [Abstract]. Dodds teaches obtaining data relating to a plurality of animal characteristics including breed, age, and blood type [Col. 11], wherein owners obtain these data by obtaining and submitting blood samples of their animals to a veterinarian (i.e. clinical pathologist) or veterinary clinic, or to a laboratory for analysis of the biological, physiological, or pathological condition [Col. 2, ¶ 2], as in claims 1, 10, and 25. Genetic data related to thyroid disease and the phenotype health assessment data is combined to determine a relationship between the genetic data and the phenotype health assessment data using a computer program [Ref. Claim 1], as in claims 1, 10, and 25. The phenotypic and genotypic information together with other database information can be presented to a user on a computer screen or other viewing means [Col. 21, ¶ 2] and [Fig. 6], which is a teaching for a computer generated report as in claims 1, 10, and 25. Communication of data occurs through a network to include remotely located clients [Fig. 1] in electronic or fax format [Col. 2, ¶ 2], as in claims 1, 3, 10, 12, and 25. Dodds also teaches phenotype and genotype databases wherein data is divided into particular groupings [Col. 21, ¶ 3 and 4], a genetic marker database [Col. 21, ¶ 6], and an algorithm that relates coefficients and predictability data (i.e. criteria) from the above data to determine an output [Col. 22, ¶ 3], and relating results from the phenotypic database to genotypic and

combined database categories (i.e. breed, age, sex, etc.) for making a diagnosis of health [Col. 23, ¶ 3], as in claim 25.

Dodds does not specifically teach obtaining a supplemental or enhanced report or a second computer program comprising menus and icons, as in instant claims 1, 3-5, 8-10, 12, 14, 17-18, 25, and 43. However, Dodds et al. teach an alternate embodiment wherein data interpretation is performed by an algorithm and outputted to user via an expert interface [Col. 21, ¶4], which suggests additional reports generated using a second program and GUIs.

Trendelenburg et al. teach a knowledge-based system (Pro M.D.) that enables medical experts to integrate their knowledge and experience with laboratory information systems to generate integrative explanatory reports [Abstract] and [Fig. 1], as set forth above. More specifically, Trendelenburg et al. teach the following aspects of the instantly claimed invention: A supplemental lab report generated by a Pro M.D. system comprising parameters and icons for thyroid disease, antibodies, disease states, treatments, and levels of immunity to disease (e.g. leukocytes) [Fig. 2 and 4], as in claims 1, 8-10, 17, 18, 25, and 43. A user-interface of a Pro M.D. system (i.e. second computer program) that enables the transfer of laboratory analytical data and permits in-window supplementation of laboratory data from expert input resulting in an enhanced report, as in claims 1, 3, 10, 12, and 25. Furthermore, said interface comprises standard Microsoft Access toolbars which include text editors, menus, and icons related to disease states [Fig. 4], as in claims 1, 4, 5, 8, 9, 10, 12, 14, 17, 18, and 25. Central laboratories for collection and analysis of all fields of data from microbiology to blood bank [Section 7.4] and lymphocyte data sets [Table 1], both of which are teachings for blood sample analysis, as in claims 1, 10, and 25. Modification of reports by experienced laboratory physicians (i.e. enhanced reports) [p.240]. The Pro M.D. software is written in JAVA [Section 5, ¶3], allowing easy extension to Internet operations. Due to the indefiniteness of claims 1, 5, 6, 10, 14, and 25,

limitations directed to the intended use of said icons are not functional aspects of the instant method and therefore have not been given patentable weight over the teachings of Trendelenburg et al.

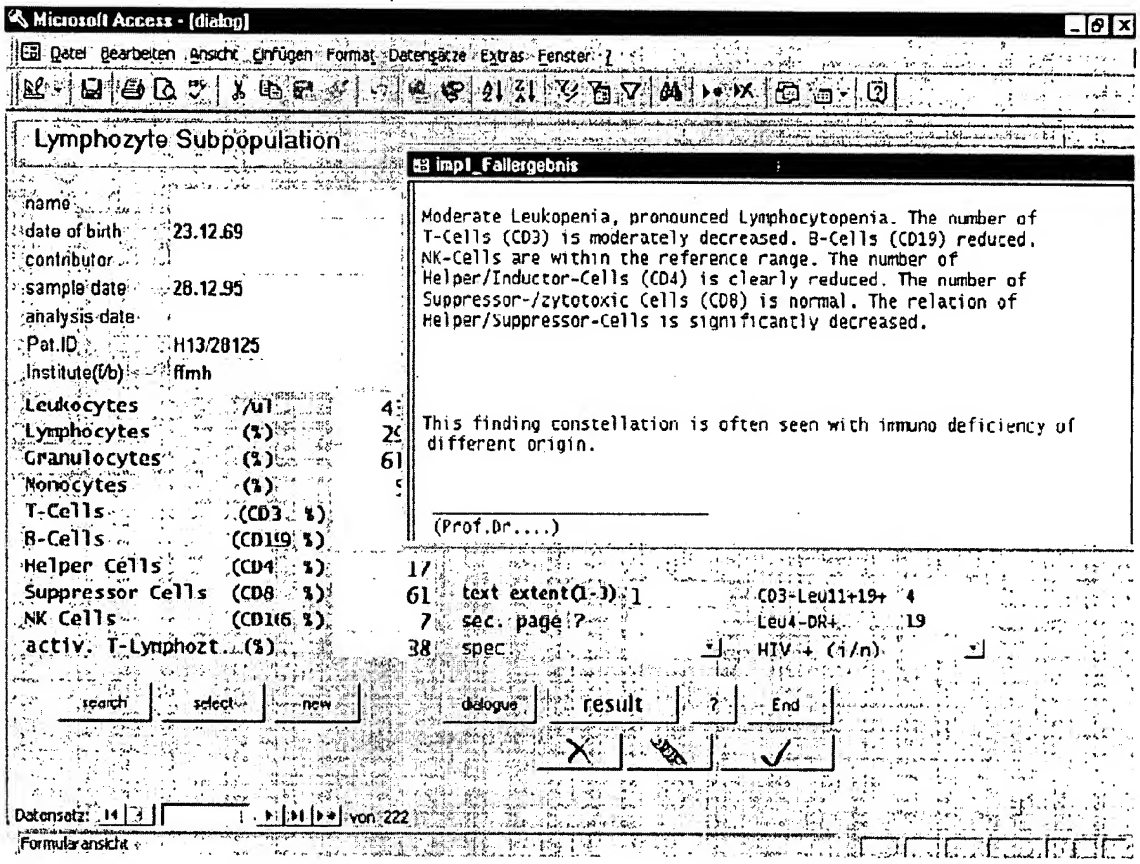

Fig. 4. Current user interface of a Pro.M.D. knowledge-based system: user input form in database Microsoft Access97.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the animal health diagnosis system of Dodds et al. using the knowledge-based interpretation program taught by Trendelenburg et al., where the motivation would have been to address the deficiency of currents tests which do not provide as much data as possible to attain correct diagnosis and disorder predictions [Dodds et al., Col. 4, ¶5], and

because of the growing demand for tools which enable the medical expert to convert his expert knowledge into computable form [Trendelenburg et al., p.230, Section 2], resulting in the practice of the instantly claimed invention. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings as all are directed to computer-based systems for data analysis.

Response to Arguments

Applicant's arguments, filed 09/07/2007, that none of the above references teaches main laboratories and the steps of a clinical pathologist; securing a blood sample; integrated reports having laboratory analysis, supplemental reports, and an enhanced report; animal disease diagnosis with characteristics unique to animals have been fully considered but are not persuasive. Applicant also argues that Trendelenburg deals with icons which are of a nature such as the conventional Microsoft word processing icons of cut, paste, print or save etc. and thus are not representative of the textual content of a report.

Dodds [Col. 1, lines 50-60] shows laboratories at veterinary hospitals or clinics are used for analyzing blood and other biological samples of a subject animal, systems for obtaining phenotype data, and communication systems for connecting these laboratories with veterinary clinics. Figure 8 shows a process by which the laboratory dynamically contributes, transmits and receives data associated with health assessment and genetic data to the CDPR. Dodds shows obtaining data relating to a plurality of animal characteristics including breed, age, and blood type [Col. 11], wherein owners obtain these data by obtaining and submitting blood samples of their animals to a veterinarian (i.e. clinical pathologist) or veterinary clinic, or to a laboratory for analysis of the biological, physiological, or pathological condition [Col. 2, ¶ 2].

Dodds shows users obtaining physical health analysis reports [Col. 21, lines 10-35] and biological reports for animals having been subject to lab analysis. Dodds also shows [Fig. 21, lines 43-55] an embodiment wherein an interpretation of both reports can be performed by an algorithm that predicts disorders and outputs the results automatically, or via an expert interface using a skilled person to interpret the data. Dodds also shows [Col. 21] that database information is animal specific and grouped by breed, family, species, disease, as well as age [Col. 11].

The icons recited in the instant claims do not result in any functional limitations of the claimed method as a whole. Accordingly, these limitations have been broadly interpreted as arbitrary design considerations that do not provide patentable distinctions over the prior art. Trendelenburg shows a supplementary report [Fig. 4] comprising icons (e.g. CD3, CD4, CD8) that represent information related to the textual data for CD3, CD4, and CD8 levels as described in the textual summary that is entered by the user. Therefore, Trendelenburg at a minimum suggests icons representative of the textual content of a report. This rejection is therefore maintained. Furthermore, claims 1 and 10 (lines 13-28) recite "obtaining from a menu on a computer screen a supplemental diagnostic report in combination with the laboratory report..." followed by a plurality of "wherein" phrases that confusingly recite active method steps and limitations of the data, the report, the menu, and icons. For purposes of examination, the Examiner has not interpreted these "wherein" clauses art not interpreted to be active method steps. Furthermore, as claims 1 and 10 do not recite any method step for generating a supplemental report, any teaching of a report on a computer screen is sufficient.

Claims 1, 3-5, 8-10, 12, 14, 17, 18, 25, and 40-45 are rejected under 35 U.S.C. 103(a) as being made obvious by Trendelenburg et al. (Clinica Chimica Acta, 1998, Vol. 278, p. 229–242), in view of Dodds (US 6,287,254; Issued: Sept. 11, 2001) and Jensen et al. (J. Comp. Path., 1996, Vol. 114, p.339-346).

Trendelenburg et al. teach a knowledge-based system (Pro M.D.) that enables medical experts to integrate their knowledge and experience with laboratory information systems to generate integrative explanatory reports [Abstract] and [Fig. 1], as set forth above. More specifically, Trendelenburg et al. teach the following aspects of the instantly claimed invention: A supplemental lab report generated by Pro M.D. (i.e. first program) comprising parameters and icons for thyroid disease, antibodies, disease states, treatments, and levels of immunity to disease (e.g. leukocytes) [Fig. 2 and 4], as in claims 1, 8-10, 17, 18, 25, and 43. A user-interface (i.e. second computer program) that enables the transfer of laboratory analytical data and permits in-window supplementation of laboratory data from expert input resulting in an enhanced report, as in claims 1, 3, 10, 12, and 25. Furthermore, said interface comprises standard Microsoft Access toolbars which includes a text editor, menu, and icons related to disease states, treatments, and levels of immunity to disease (e.g. leukocytes) [Fig. 4], as in claims 1, 4, 5, 8, 9, 10, 12, 14, 17, 18, and 25. Central laboratories for collection and analysis of all fields of data from microbiology to blood bank [Section 7.4] and lymphocyte data sets [Table 1], both of which are teachings for blood sample analysis, as in claims 1, 10, and 25. Modification of reports by experienced laboratory physicians (i.e. enhanced reports) [p.240]. Due to the indefiniteness of claims 1; 5, 6, 10, 14, and 25, limitations directed to the intended use of said icons are not functional aspects of the instant method and therefore have not been given patentable weight over the teachings of Trendelenburg et al.

Trendelenburg et al. do not teach steps directed to obtaining data relating to physical characteristics of an animal, securing a blood sample from an animal, or icons related to animal characteristics, as in claims 1, 8, 9, 10, 17, 18, 25, 40-42 and 44-45. Trendelenburg et al. also do not teach communication via a network, as in claims 1, 3, 10, 12, and 25, but do teach software written in JAVA [Section 5, ¶3], allowing easy extension to Internet operations.

Dodds teaches a veterinary diagnostic method, system and apparatus of health profiling of an animal subject [Abstract], as set forth above, wherein communication of data occurs through a network to include remotely located clients [Fig. 1] in electronic or fax format [Col. 2, ¶ 2], as in claims 1, 3, 10, 12, and 25.

Jensen et al. teach immunoradiometric assays and commercial test kits for evaluating dogs with thyroid disease [Abstract]. Blood samples are obtained from healthy and diseased dogs [Table 1]. Jensen et al. teach groupings of data sets comprising large and small breeds of dogs, German shepards (which the Examiner has broadly interpreted as sight hounds as they are well-known to be used as seeing eye dogs), clinical descriptions of dogs and disease status, age, sex, and TSH (i.e. thyroid disease) concentration levels [Table 1], which is a teaching for grouping of animal characteristics, as in claims 1, 8, 9, 10, 17, 18, 25, 40-42 and 44-45. It is noted that claims 40-42 and 44-45 are directed to "groupings" and do not specifically recite any functional limitations directed to grouping of "icons." Therefore claims 40-42 and 44-45 have not been given patentable weight over the teachings of Trendelenburg et al. and Jensen et al.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice knowledge-based test result interpretation program taught by Trendelenburg et al., using the animal and disease attributes taught by Jensen et al. as icons, as the system of Trendelenburg et al. enables experts to use their own knowledge and notation [Trendelenburg et al., Section 2, ¶ 3]. One of ordinary skill in the art would have been motivated

to combine the above teachings because of the growing demand for tools which enable the medical expert to convert his expert knowledge into computable form [Trendelenburg et al., p.230, Section 2], resulting in the practice of the instantly claimed invention. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings as all are directed to computer-based systems for data analysis.

Response to Arguments

Applicant's arguments, filed 09/07/2007, that Trendelenburg deals with icons which are of a nature such as the conventional Microsoft word processing icons of cut, paste, print or save etc. and thus are not representative of the textual content of a report have been fully considered but are not persuasive. Applicant's arguments that none of the above references teaches main laboratories and the steps of a clinical pathologist; securing a blood sample; integrated reports having laboratory analysis, supplemental reports, and an enhanced report; animal disease diagnosis with characteristics unique to animals have been fully considered but are not persuasive. Applicant's arguments that Jensen does not teach an assay that is adequate for determining thyroid disease or grouping of animal of adult, puppy, and large breed dog are not persuasive.

The icons recited in the instant claims do not result in any functional limitations of the claimed method as a whole. Accordingly, these limitations have been broadly interpreted as arbitrary design considerations that do not provide patentable distinctions over the prior art. Trendelenburg shows a supplementary report [Fig. 4] comprising icons (e.g. CD3, CD4, CD8) that represent information related to the textual data for CD3, CD4, and CD8 levels as described in the textual summary that is entered by the user. Therefore, Trendelenburg at a minimum

suggests icons representative of the textual content of a report as required. Trendelenburg also shows their object oriented system is designed for internet operations and is adaptable to support new knowledge bases [Section 5] based on the user specific knowledge. Therefore it would have been well within the capabilities of one of ordinary skill in the art to modify the Pro MD system to incorporate other types of laboratory and diagnostic data.

Dodds [Col. 1, lines 50-60] shows laboratories at veterinary hospitals or clinics are used for analyzing blood and other biological samples of a subject animal, systems for obtaining phenotype data, and communication systems for connecting these laboratories with veterinary clinics. Figure 8 shows a process by which the laboratory dynamically contributes, transmits and receives data associated with health assessment and genetic data to the CDPR. Dodds shows obtaining data relating to a plurality of animal characteristics including breed, age, and blood type [Col. 11], wherein owners obtain these data by obtaining and submitting blood samples of their animals to a veterinarian (i.e. clinical pathologist) or veterinary clinic, or to a laboratory for analysis of the biological, physiological, or pathological condition [Col. 2, ¶ 2]. Dodds shows users obtaining physical health analysis reports [Col. 21, lines 10-35] and biological reports for animals having been subject to lab analysis. Dodds also shows [Fig. 21, lines 43-55] an embodiment wherein an interpretation of both reports can be performed by an algorithm that predicts disorders and outputs the results automatically, or via an expert interface using a skilled person to interpret the data. Dodds also shows [Col. 21] that database information is animal specific and grouped by breed, family, species, disease, as well as age [Col. 11]. Jensen shows [Table 1] groupings of data sets specifically for large and small breeds of dogs, clinical descriptions of dogs, disease status, sex, and TSH (i.e. thyroid disease) concentration levels. Jensen also shows a range of ages from 1 to 11 years, which is suggestive of puppy and adult groupings. Therefore, it would have been well within the

capabilities of one of ordinary skill in the art to use icons for graphical representation of grouped data parameters. This rejection is therefore maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JSB 26 November 2007

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER